Pharmacy Medical Necessity Guidelines: 
Vivitrol® (naltrexone extended-release injection)

Effective: June 1, 2017

<table>
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<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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Not Covered

Pharmacy (RX) or Medical (MED) Benefit

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<th>Department to Review</th>
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<td>MED</td>
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Fax Numbers:

RXUM: 617.673.0988

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Direct – Health Connector**
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

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RXUM: 617.673.0988

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

**Alcohol Dependence**

Vivitrol (naltrexone extended release injection) is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol. Patients should not be actively drinking at the time of initial Vivitrol administration.

**Opioid Dependence**

Vivitrol (naltrexone extended release injection) is indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Vivitrol for Members when all of the following criteria are met:

1. The Member has a documented diagnosis of alcohol dependence OR the Member has a documented diagnosis of opioid dependence and has completed opioid detoxification

2. The Member is currently abstaining from opioids

3. Psychosocial support is part of the recommended treatment plan

4. The Member has tried and failed a trial with oral naltrexone and an allergy to naltrexone been ruled out

5. The Member has been stable on Vivitrol for a period of at least 3 months prior to this prior authorization request.

**LIMITATIONS**

1. Vivitrol will not be covered for Members who are concurrently taking any opioids. The provider must indicate the recent opioid use was prior to the completion of a recent detoxification in Members found to have pharmacy claims which indicate that the member has received an opioid within the past 30 days or could have used an opioid within the last 10 days.

2. Initial authorization will be limited to one year as follows:
   a. Vivitrol (naltrexone extended release injection) 380 mg: 1 vial per 28 days.

3. Subsequent authorizations will be provided when the following criteria are met:
   a. Psychosocial support is part of the recommended treatment plan AND
   b. Alcohol Dependence: The member is currently abstaining from alcohol and opioids or the provider documented a significant reduction in the amount of drinking or medically related services such as detox or ER visits OR
   c. Opioid Dependence: The member currently abstaining from opioid use.
CODES
The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J2315</td>
<td>Injection, naltrexone, depot form, 1 mg</td>
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REFERENCES

APPROVAL HISTORY
April xx, 2017: Reviewed by Pharmacy & Therapeutics Committee.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.
This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.